



COMMITTEE ON ENERGY AND COMMERCE

Chairman Fred Upton
114th Congress

The 21st Century Cures Act (HR 6) **Help and Hope for Patients Through Biomedical Innovation** *(Passed the House by a vote of 344-77 on July 10, 2015)*

The pace of scientific advancement over the past two decades, including the mapping of the human genome, has been impressive, giving us a myriad of genetic clues about the underpinnings of disease. Translating these discoveries into new treatments for patients, however, has proven to be difficult. HR 6 accelerates the discovery, development and delivery of life saving and life improving therapies, and transforms the quest for faster cures by:

- **Removing barriers to increased research collaboration.**

Experts agree that more collaboration and access to data will produce faster cures and therapies. While protecting patient privacy, HR 6 breaks down existing barriers to sharing and analyzing the growing amount of health data generated in research and clinical settings.

- **Incorporating the patient perspective into the drug development and regulatory review process.**

HR 6 strengthens the FDA's ability to take the direct experience of patients with particular diseases and conditions, and the effect of their current therapies and use that data to modify and improve potential treatments.

- **Measuring success and identifying diseases earlier through personalized medicine.**

HR 6 provides guidance for the broader, more collaborative development, understanding, and utilization of drug development tools such as biomarkers, which can be used for earlier assessment of how a particular therapy is working and on whom. HR 6 would advance personalized medicine, making sure patients can be treated based on their unique characteristics at the appropriate time.

- **Modernizing clinical trials.**

Personalized medicine allows researchers to design more targeted clinical trials that can produce results faster and cheaper. HR 6 will allow greater use of patient generated registries that speed the recruitment of participants. It will also allow researchers to screen patients in advance to determine if their genetic predisposition makes them better candidates for targeted therapies. The legislation also clears the way to use new and creative adaptive trial designs and deploy the most modern statistical and data tools, while significantly reducing existing, duplicative or unnecessary paperwork requirements.

- **Removing regulatory uncertainty for the development of new medical apps.**

Regulatory uncertainty has slowed the development of medical apps that generate real time patient data. These apps hold tremendous promise for improving healthcare—saving time, money, and lives. HR 6 provides more certainty for app developers, clarifying their regulatory path moving forward and will speed the creation and deployment of these innovative health tools.

- **Providing new incentives for the development of drugs for rare diseases.**

Small populations and a lengthy development process often make the discovery of treatments for rare diseases and conditions challenging. HR 6 creates new economic incentives for the development of therapies for serious and life threatening conditions, including rare diseases. New incentives will translate to more, faster cures.

- **Helping the entire biomedical ecosystem coordinate more efficiently to find faster cures.**

Finding new cures and therapies requires more than a discovery in a laboratory. HR 6 creates a new coordinating mechanism to remove the choke points that slow the connections between scientific discovery, drug and device development, and how these therapies are approved and made available to patients. HR 6 improves the entire biomedical ecosystem ensuring the innovation infrastructure works as quickly and efficiently as possible.

- **Investing in 21st century science and next generation investigators.**

HR 6 creates the “Innovation Fund,” a dedicated and offset funding stream of \$1.75 billion per year for 5 years for the NIH and \$110 million per year for 5 years for the FDA that will allow congressional appropriators to invest additional resources without impacting current budget caps. Since experts believe investments in younger scientists will speed the discovery of new cures, HR 6 also includes provisions to invest more resources in the next generation of scientists for the next generation of drugs.

- **HR 6 helps keep and create jobs here at home.**

HR 6 is not only a patients bill; it is a jobs bill. The United States has led the global medical device and biopharmaceutical industries for decades, helping us become the medical innovation capital of the world and causing China and others to try to take our innovation and jobs. Because of our leadership, U.S. medical device-related employment totals over 2 million jobs, and the U.S. biopharmaceutical industry is responsible for over 4 million U.S. jobs. NIH funding currently supports over 400,000 jobs at research institutions across the country, including jobs for young scientists. The policies in HR 6 will help us fight off foreign competitors so we can keep these jobs, and add more, here at home.

- **HR 6 reduces the deficit by over \$500 million.**